FINAL TRANSCRIPT

Thomson StreetEvents℠

ACAM - Q1 2005 Acambis plc Earnings Conference Call

Event Date/Time: May. 10. 2005 / 4:30AM ET

CORPORATE PARTICIPANTS

Gordon Cameron
Acambis Plc - CEO

David Lawrence
Acambis Plc - CFO

CONFERENCE CALL PARTICIPANTS

Peter Welford
Merrill Lynch - Analyst

Steve McGarry
Goldman Sachs - Analyst

Chris Redhead
Code Securities - Analyst

Robin Gilbert
Numis - Analyst

Sam Visarli
- Analyst

Robin Campbell
Jefferies - Analyst

PRESENTATION

Operator

Good day ladies and gentlemen. And welcome to the First Quarter 2005 Acambis Earnings Conference Call. My name is Alisha and I will be your operator. [OPERATOR INSTRUCTIONS]. I would now like to introduce your host for today's call, Mr. Gordon Cameron, Chief Executive Officer. Please go ahead.

Gordon Cameron - *Acambis Plc - CEO*

Thank you and welcome to the First Quarter Results for Acambis in 2005. Gordon Cameron speaking here. I'm also joined by David Lawrence, our Chief Financial Officer. I hope for those of you who have access to our slides, they are on the website, so what I'll do is I'll take each slide as I go, and endeavor to remember to say 'next slide'.

So the first slide is obviously the cover slide, so if you go to slide 2, I'd draw your attention to the Safe Harbor statement in relation to some forward-looking statements that may be made during the course of this web cast.

On the next slide 3, the Agenda for today. I'll cover some of the key points and then update some of the aspects from an operating standpoint. I'll then turn it over the David, who will cover the financials and then comment on the IFRS situation. And then we'll turn the call over to a question and answer session.

On slide 4, on the key points, what we've done here really is lay out in the same way as we do in our Annual Report, that's just been published, and also the prelim results from a few weeks back, and also internally our 4 core strategic goals and what we're trying to do this year and beyond. And we categorize this in terms of our goals and have laid them out, and also commented on the right-hand side the progress that we're making towards those.

In terms of exploiting the smallpox franchise, we do have one base manufacturing discussions ongoing with the U.S. Government which I'll come onto. The MVA RFP the draft for comments is going to be issued shortly, and this again I'll comment on. And then the investigational products is now an approved product for the VIG owned by Cangene that we distribute. So there's 3 key areas of progress on the smallpox franchise.

New products, I think you'll see today that we've met all our milestones and the targets for 3 of the development stage projects, MVA, West Nile and the C. diff, so we're moving forwards with those products.

In terms of developing out core capabilities, I'm going to talk about an acquisition of fill/finish capacity that we announced today.

Plus in terms of improving predictability of the earnings stream, not only are there strong year-on-year growth of Vivotif sales, the warm-base manufacturing we could arguably within this category as well, but we're also continuing to pursue other product opportunities.

So we move onto the next slide, starting first of all with our fill/finish acquisition. What we've acquired here is outlined both in a separate press release and referenced in the main results today, that we've acquired today an Lyophilisation -- or freeze drying -- fill/finish facility from a Company called BioReliance, which is part of the Invitrogen Group. The terms of it are that we're going to pay $3m cash upfront, plus an additional $4.5m spread in 12 equal installments over the next 12 years, which coincides with the term of the lease.

From a rationale standpoint. From what we've been seeing for some time is that we're intending to put in place and become a fully integrated company. This completes the supply chain that we had previously manufacturing capacity and capability at Canton, Massachusetts, specifically for making bulk vaccine. What we now have is a fill/finish capability, and that completes the supply chain from that standpoint. Obviously we've got better control over our timelines, we're not reliant on sub-contractors in terms of their own timelines are priorities, and an additional knock-on from that is that we're also going to retain more manufacturing margin, again that the sub-contractor would otherwise have captured.

For our proposal that we put to the U.S. Government on warm-base manufacturing, to have a capability over the longer term with [key] is part of that, so this is the final piece of the jigsaw for that for having longer-term warm-base manufacturing capability, and based in the U.S. which is an important criteria for the U.S. Government.

In terms of a suitability obviously [indiscernible] ACAM2000, has capability to fill and finish our MVA products, the Japanese Encephalitis vaccine, the West Nile Vaccine and the potentially the C.difficile Vaccine as well. So there's broad capability on this facility.

In terms of the next slide. A little more detail what's actually in the facility in slide 6. It's a modern -- it was built in 2000 and fitted out in that period, and actually some additional equipment's been installed more recently than that. It's a 58,000 square foot facility in Maryland in the U.S. It's fill/finish capability but also some small scale manufacturing process development suites in there as well. There's around 13,000 square feet of unfinished space that we could potentially expand into at a later date, should we need to. So the capability today is for clinical scale material, both liquid and freeze-dried fill material. There is an intention to have an expansion plan to upgrade it to full-scale commercial scale over the next coming 6 to 12 months.

There isn't actually any employees involved in this acquisition. Activity at this plant has been wound down by the previous owner over the last 6 to 9 months. So we will be seeking to recruit people over the course of the next coming months and year or so. We will, as part of the transitional arrangements, utilize existing employees that we have in the Canton Massachusetts facility to -- as part of the whole implementation plan in getting the site up and running. And the employees we envisage being employed there are obviously in manufacturing operations but also in the quality side of the fence as well.

If we go to the next slide in terms of the -- just going on briefly what I've referenced before that there'll be an expansion program and an upgrading of scale around the -- involving capital investment somewhere in the order of $4m - $6m over the next 12 months spread between 2005/2006. And that will give us commercial scale GMP-compliant operations.

So there will be some shorter-term expenditure in terms of operating costs to, not only get the facility up and running, but in the near term that we envisage over the medium to longer term, this will be more than offset by savings in subcontractor costs that we'd otherwise incur. So, as I said, this is a facility that can apply to all of our proprietary programs on the MVA specifically, Baxter our manufacturing partner has responsibility for fill and finishing MVA, but obviously this could provide a back up or alternative to sit alongside that, certainly strengthen the Partnership's hands in our discussions with the U.S. Government.

If you move onto slide 8, on MVA specifically and the internal product branding name is for the time being as a development product, is MVA3000, so you'll see it referenced as that for the time being. We announced a couple of weeks ago some data on the initial trial for MVA at around 110 naive subjects -- naive to smallpox vaccination. 88 received our MVA products, 22 received a placebo, and the sero conversion rate that we achieved are outlined in the slide, there's 97% in the ELISA test and 82% in the PRNT test, after 2 doses, were very much in line with what we expected, and are consistent with other previously published data on MVA, by both ourselves and other companies.

No serious adverse events were reported, and as I said, very much in line with our expectations. So we're moving forwards a pace with the Phase II trial in healthy adults which is a sense there of a larger safety and immunogenicity trail in the coming weeks, and in addition moving into the trials for the target population in this case HIV subjects and those suffering from atopic dermatitis. All of these trials as part of the NIH contract to develop and supply MVA vaccine.

To move onto slide 9, there's obviously continued speculation about when the RFP for the upcoming supply contract will be issued. We did get some visibility on the process 10 to 12 or so days ago, when testimony was given to the Senate Appropriations Committee on Homeland Security by the Assistant Secretary of the Office of Public Health Emergency Preparedness. And he, at the time, as part of that statement signaled, we've put the quote in the statement and on the slides here that we "intend to acquire a next generation smallpox vaccine, and will be releasing a draft RFP for industry comment within the next 2 weeks". This is a clear signal that the process is beginning. We anticipate this draft will come out, we'll be given a week a 2 to comment on it and then they will choose to incorporate or not any industry comments, and then the final RFP will be issued shortly thereafter.

So the timing on this, as I say, we now have some more visibility than perhaps we had a month or 2 ago, and the timing is bang in line with the expectations that we stated all along, that we expected the RFP to be issued in the first half of the year. The contract award would be made in the second half of the year.

Moving onto the next slide 10, in terms of covering the other aspects of the smallpox franchise. On ACAM2000 the data from the Phase III trials is being analyzed and assembled, both from these trials and from the previous trials, in preparation for the pre-BLA meeting that we're expecting in the third quarter this year. So that remains on track to file the BLA in the second half of the year, as previously stated.

The warm-base manufacturing discussions are ongoing with the CDC. We recently made an additional presentation to the Department of Health and Human Services, so we anticipate that they'll be some kind of decision made on that, hopefully fairly soon.

The fill/finish facility, as I mentioned before cross-referencing to that, this now gives us a fully integrated supply chain on the U.S soil. Clearly from the U.S. Government's perspective that was a clear preference from their part. And as I say, it's the final piece of the jigsaw as part of our warm-base manufacturing proposal.

As I mentioned earlier on in the beginning, the Vaccinia Immune Globulin product owned by Cangene and the [indiscernible] which we distribute around the World, that was recently approved by the FDA, so that should facilitate further sales of that product.

On to the next slide, Vivotif our oral typhoid vaccine that's distributed by Berna Products in the U.S, like last year, our sales are again ahead of the previous year. In the first quarter the sales were ahead of the equivalent period in 2004. We did benefit from the fact that the competitor product was off the market for part of the quarter, and then we were able to catch additional market share from that. We are also continuing to pursue other in licensing our business development type activities to put other products through that distribution channel. Obviously it's going very well at the moment, in terms of selling that one product that we continue to believe that infrastructure would benefit from having further products going through it. So as I say, we're continuing in some discussions in relation to that.

Slide 12 in terms of the R&D update on the other projects. Bang on track with the ChimeriVax-JE. The bridging trial we've actually completed the clinical phase for this, the serology and other analysis are underway right now. So we're bang on track to initiate the Phase III trial in the second half of the year, as we previously stated.

And just another point, we've had another trial ongoing as part of the overall package of data to drill ultimately into the license application [a duration of unity study] that is potentially looking at seeing how long the immune response lasts in subjects over a longer period of time. And the data we have so far is that the neutralizing anti-body levels remain at a high level at both 6 and 12 months after a single vaccination. So again, this supportive data to our long-held belief that the ChimeriVax-JE will be effective as a single dose vaccine, which is going to give a clear competitive advantage over other products, both in development and on the market today.

Turn to slide 13. Move onto ChimeriVax-West Nile. We published today the full results from the Phase I trial, for which we reported results from the first cohort several months back. So this is the complete data from the 80 subjects safety and immunogenicity trial, of which 45 of those subjects received 1 of 2 dose levels of West Nile vaccine, 30 subjects got the placebo and 5 subjects got the Yellow Fever vaccine in the first cohort of the trial.

And as pointed out here, the results are reinforced the earlier results we got from a small number of subjects in the first cohort, where we got 96% and 100% sero conversion neutralizing antibody generation at the higher and lower dose respectively. There was a serious adverse event which we already referenced several months back. It was in relation to [CPK] elevations which we subsequently confirmed or certainly believed was non human related or non vaccine related and we actually -- there was a paper published in Human Vaccines in relation to that particular finding.

So we will be presenting in more detail the results at a National Foundation of Infectious Diseases Conference in Baltimore tomorrow. Our Chief Scientific Officer, Tom Monath, will be presenting that data tomorrow. So there will be more complete data available at that conference. But in the interim, we are moving forward with both the clinical development plan and also the manufacturing of the product. We are now making this product at our facility in Massachusetts, that process of transferring the vaccine from the previous manufacturer to our facility. We optimize the formulation of the vaccine and we'll be using this new product manufactured at our facility in the next trial. So we will amend the existing IND in relation to the new manufactured product at our facility, and initiate the next trial in the second half of this year, which we envisage will be a larger safety and immunogenicity trial at various dose levels.

And the next slide, R&D update, slide 14. On the C.difficile again right in line with what we said. We are prepared to initiate the first of 2 Phase I trials very shortly. The initial trial will be in healthy subjects, and the second Phase I trial which we anticipate will start shortly thereafter will be in elderly subjects. We recently have been working closely with the CDC actually, and we presented data at a recent conference at the Society of Health Care and Immunology in April, indicating that there appears to be a more virulent or higher level of A and B toxins circulating in the recent cases of C.difficile, which doesn't necessarily impact on the ability of our vaccine to protect against this infection, but does indicate that there are cases both the number and the severity of the cases of C.difficile are increasing in this particular case.

ARILVAX, nothing really further to add. Just included for completeness, other than to say that discussions are ongoing with Chiron, in relation to the production or otherwise of our ARILVAX at their facility in Liverpool.

Out licensing, and this is for – as you recall we stopped investing in a couple of projects in 2004 as part of our portfolio review, we have out licensed 1 of those products, our ETEC vaccine to a Company called Cambridge Biostability Limited. Terms weren't disclosed. But I think an important thing, is that we've retained an option to market this product, if and when that product gets to license by Cambridge Biostability or any of its partners, we will retain an option to market the product in North America, obviously through our Berna Products infrastructure.

So on the R&D side of things, I think the key message is we're bang on track with all the milestones that we've set ourselves, both for the first quarter and first half of the year, and an anticipated milestones in the second half of the year.

So I'll just hand over to David now who'll cover the financial piece of this before returning back to me at the end.

David Lawrence - *Acambis Plc - CFO*

Thanks Gordon. Good morning everyone. So I'll start from slide 15. This is the first time we've reported the numbers under the new International Financial Reporting Standards and therefore the [indiscernible] we published this morning we've restated our 2004 Q1s and full year numbers under IFRS. We've made that our accounting policies and reconciled our IFRS numbers to those previously reported under U.K GAAP.

Although there are some changes in the presentation today, [a lot of] what you'll see is that overall, IFRS has a very limited impact on our numbers. There's also no cash impact, and more importantly, we haven't felt the need to change our business practices as a result of moving over to IFRS, although we know that many other companies review our compensation approach noting that direct impact in the P&L of share options costs.

And I'll come onto the details of IFRS after we've gone through the numbers. I've just laid out in this slide the 6 IFRS standards of greatest relevance to our business today. I expect these will be familiar to many of you already as I believe our experience is very similar to that of other firms, and biotech companies. And the 2 of most noticeable relevance today IFRS 2 and IFRS 3, but the overall impact is broadly neutral.

So moving onto the numbers, let's start with slide 16. So the P&L for example is now known as an Income Statement, but the specific line items still look very familiar. Revenue in the quarter was £6m. That included work ongoing under ACAM2000 contract, MVA RFP1 and RFP2 and so [indiscernible]. And as Gordon mentioned actually, we've had a good start to the year in term of sales of [Berna] products. The reduction compared to Q1 2004 is due to the fact that we're nearing the successful completion of ACAM2000 contract facilities under the old CDC contract.

Cost of sales for the Group decreased in line with the level of activity required for ACAM2000, giving us a gross margin for the period which is very similar to the same period in 2004.

The R&D and SG&A cost lines were in line with our expectations. The key things to note here are the admin line in 2004 included charges related to the restructuring of U.K. Research and excludes some goodwill amortization under IFRS 3, which I'll will come back to talk about in a minute. At the same time the share option charge under IFRS 2, is allocated to different cost lines in line with where the staff are employed in the business. As I mentioned before the 2 impacts have a broadly neutral effect.

An increase in net interest over 2004 levels reflects our strong cash position and higher interest levels than last year. Bearing in mind that most of our cash is held in the U.K. Levels of pre-tax loss for the period £5.8m and a tax credit of £1.4m. This shouldn't be a surprise here this is exactly in line with a year of investment, which we talked about at the prelims when we gave some guidance for the year.

So slide 17, moving onto the cash flow highlights. So what you see here is that the working capital movements becoming less significant, as we enter the final stages of the ACAM2000 CDC contract. High level of tax paid in Q1 reflects final payments relating to 2004. CapEx [indiscernible] normalized levels during the quarter, but the given the acquisition that we've announced today, and that Gordon's been talking about, while we've got plans to upgrade and expand the fill/finish facility, CapEx will increase later in the year. Gordon mentioned already, but they're be plans to invest around $4 to $6m over 2005 and 2006 on this facility.

So finally, the Balance Sheet on slide 18. So the cash continues to be strong standing at £94.3m at March 31. The main changes, as I've mentioned already, basically tax and operating costs. On the [indiscernible] side deferred income on CDC ACAM2000 contract is used to reduce outstanding just under £14m. And the reduction of our creditors you can see on the page there is mainly driven by tax being paid.

Right, if you move to slide 19, it just talks a little bit about IFRS. So I'll come on to the detail of IFRS 2 and 3 in just a second. But the question of capitalization of R&D under IFRS 38 in line with the rest of the industry, we could say it's not possible to demonstrate [technical] feasibility and the projectable [indiscernible] economic benefits until regulatory approval, and as such, we don't satisfy maybe all the criteria required for capitalization of intangible assets, therefore we won't be capitalizing R&D.

As concerns Financial Instruments under IAS 32 and 39. The 1 area of importance for us there is the [indiscernible] relating to hedging which now requires additional documentation. Given our [inaudible] we won't be looking at any major changes in either. And on IAS 12 Income tax, there are some temporary deferred tax differences arising as a result from the application of IFRS to [indiscernible] and that's has an effect in issuing comparative [indiscernible] rates.

On slide 20 I look to the first of the [criterias] of particular relevance to Acambis. So unlike U.K. GAAP goodwill is no longer amortized under IFRS 3 and this is relevant to Acambis in terms of acquisitions, so for Acambis Inc. and Berna Products. The Acambis impact that we would expect [indiscernible] is simply frozen the goodwill and that is effect in increasing the [gross] profit by £1.2m per annum.

For the Berna Products [acquisition] which is more recent, we've been able to identify the relevant intangible assets which continue to be amortized and this is reflected in the Balance Sheet as a new intangible asset and non current assets. As an [indiscernible] assets an annual impairment due on both intangibles and goodwill.

Slide 21 reflects the share based figures. Under IFRS 2 a charge will be made to the [perceived] calculated value of the share option grants, using the provisions for transitions between U.K. GAAP and IFRS we are applying this charge only to options, and not to [indiscernible] 2002 that had not vested by 2003.

We expect the ongoing impact of the share charge of up to £1m a year. This means the overall picture [indiscernible] by the ending of the amortization of goodwill for Acambis Inc. So I'll try and clarify those on the Q&A. And I'll hand back to Gordon now to summarize the [indiscernible] and a look at the rest of the year.

Gordon Cameron - *Acambis Plc - CEO*

Okay. Thank you David. I think we've been pretty transparent of the goals that we set ourselves in documentation externally, but also internally as well there absolutely consistent with what we say externally. So I think what we've done in the first quarter is very much in line with the objectives of the goals we set ourselves and ensure that we're on track to deliver those and for the remainder 2005 as well.

The ACAM2000 pre-BLA meeting is planned as previously stated for the third quarter. We are awaiting decision from CDC on warm-base manufacturing proposal I alluded to earlier on, that the fill/finish aspect I think is the final piece of that jigsaw.

The draft MVA, we do have some more visibility on that and we expect that shortly for comments, we continue to believe we're extremely well positioned for that, particularly with the manufacturing capability that we have with our partner Baxter, which has an infrastructure in place today, and we're meeting blue scale commercial scale MVA.

Planned pipeline progress over the rest of the year, or in terms of the key things we should be looking out for, starting the MVA trials for Phase II and also the Phase I for the target population. Moving ahead to the C.difficile program getting that back into the clinic, and as I said becoming increasingly important given the prevalence of that particular disease or the increase in prevalence of it.

Bridging trial for JE will be completed -- the clinical pieces of the trial I'm just finalizing the analysis so we can start the Phase III testing in the second half of the year. And moving forwards with the West Nile trial. We were the first to go into the clinic with our West Nile vaccine. We were the first to record data for West Nile vaccine, so we're ahead of the competition and we intend to stay ahead of the competition.

And we'll continue to look at a number of business development opportunities. So those will come to fruition as and when the deals gets closed. So I think it's fair to say that we wouldn't be saying this, if we didn't believe that we were going to be able to close some of these deals.

So I think in terms of the outlook for 2005 everything's on track. And I'll throw the question -- both David and I will throw the call open to questions.

QUESTIONS AND ANSWERS

Operator

[OPERATOR INSTRUCTIONS]. The first question comes from the line of Peter Welford with Merrill Lynch.

Peter Welford - *Merrill Lynch - Analyst*

Hi. 2 questions on the financials actually. Firstly on the revenues. Given the fact that the first quarter revenues were around £6m, do you still feel that you're on track for your revenue target that you set at the full year results, excluding -- I think you excluded Smallpox or MVA revenues?

And secondly, can you just outline what sort of level do you think operating expenses could be this year, if they're going to be impacted this year by the acquisition of the fill/finish facility? And then what sort of incremental amount we can look forward to in the future years when the employees are fully recruited?

David Lawrence - *Acambis Plc - CFO*

On revenue, I think when we delivered prelims we talked about a number of things probably in the second half, including some of the less predictable things like warm-base. So my answer to you, Peter, is that we're not changing our guidance at this stage.

In terms of operating expenditure, particularly related to the new facility, the operation that we've just acquired and announced today. During this year we're having a number of discussions with the CDC about the warm-base contract and I think, therefore, it wouldn't be entirely appropriate to give numbers that might influence that discussion. So, I won't really comment in detail [inaudible].

What I can say is that the majority of expenses will be capitalized during 2005, and certainly the first part of 2006, as we upgrade the facility and expand it. That's [indiscernible] sound accounting practice. And then the ongoing costs are likely to be driven by a mixture of things that happen there, including the volume and the mix of things that go through it in terms of products. This is going to cover more than 1 product and it will really depend on the [indiscernible] of that. So I'm not going to give you any details now Peter.

Peter Welford - *Merrill Lynch - Analyst*

Okay. Sorry, just another quick follow up. You're bookings are I understand then you will book the $3m [indiscernible] payment this year? And then you'll book most of that $4 to $6m capital investment this year. So that's the $4.5m will be booked over the next 12 years? Is that right?

David Lawrence - *Acambis Plc - CFO*

$3m upfront that'll clearly come out of cash.

Peter Welford - *Merrill Lynch - Analyst*

Yes. And then roughly the $4 to $6m capital investment will also come out of cash mostly this year?

David Lawrence - *Acambis Plc - CFO*

That will be across 2005 and 2006.

Peter Welford - *Merrill Lynch - Analyst*

Okay. Sorry. Okay, that's great.

David Lawrence - *Acambis Plc - CFO*

And then the $4.5m is 12 equal installments over the 12 years that remain on the lease.

Peter Welford - *Merrill Lynch - Analyst*

Okay. That's great. Thank you.

Operator

The next question comes from the line of Steve McGarry with Goldman Sachs. Please go ahead.

Steve McGarry - *Goldman Sachs - Analyst*

Good morning gents. Just a couple of questions. [indiscernible] down on the revenues in a bit more detail. Obviously in the first quarter you didn't really book -- we assume you didn't book a great deal of revenues from the second MVA contract, which is obviously much larger than the first 1. Can we make the assumption given that you've got a requirement of over half a million

doses of vaccine for the Government by the end of August, which is clearly the majority of the MVA revenues from the second contract in the second and third quarter?

David Lawrence - *Acambis Plc - CFO*

I think that's a reasonable and fair assumption Steve.

Steve McGarry - *Goldman Sachs - Analyst*

Okay. Secondly, on the West Nile virus trials. You said you've got another trial with safety and immunogenicity at various doses. Firstly will the FDA accept that safety and immunogenicity is a [primary] end point and how many patients do you think you'll actually need to get this one through the FDA?

Gordon Cameron - *Acambis Plc - CEO*

The last question's difficult to answer at this stage. Most of the trial numbers -- the big trial numbers in Phase II are often driven by safety rather than immunogenistic. And in fact what we envisage with the West Nile vaccine, is the neutralizing antibodies will be a measure for efficacy but they'll be supported by animal [indiscernible] data as well. So [indiscernible] had any discussions there's a plan that we would do both large scale safety and immunogenicity trials and animal [indiscernible] probably along side it.

Steve McGarry - *Goldman Sachs - Analyst*

Okay. And on the BioReliance facility we [indiscernible] 2017 can we make the assumption that the terms of lease won't be that onerous for you up until that point?

Gordon Cameron - *Acambis Plc - CEO*

Yes, it's a relatively low rent. The additional payments are to BioReliance are part of the consideration, but the actual outgoings in terms of rent through that lease are relatively low.

Steve McGarry - *Goldman Sachs - Analyst*

And do you have any options to acquire the facility?

David Lawrence - *Acambis Plc - CFO*

So basically there are some break points in the existing lease that would allow us to do that.

Steve McGarry - *Goldman Sachs - Analyst*

And is there a pre-agreed level that you could spend to acquire that facility at various break points?

David Lawrence - *Acambis Plc - CFO*

Yes there is.

Steve McGarry - *Goldman Sachs - Analyst*

Any guidance?

Gordon Cameron - *Acambis Plc - CEO*

No, I'm not going to give you guidance on that.

David Lawrence - *Acambis Plc - CFO*

But I think generally when you buy out something you have to part compensate for many years of leases etc. I think for the time being we're quite happy with the arrangement, in terms of most people lease these types of facilities and obviously own their own equipment.

Steve McGarry - *Goldman Sachs - Analyst*

Okay. Final 1. Just obviously your own fill and finishing, you will get the [indiscernible] plans going forward. Is there any way you could say if you look back at some of the work that you've done already, if you already had this facility in place, what kind of margin impact would you have got?

David Lawrence - *Acambis Plc - CFO*

Difficult to be precise I think there. I think -- very difficult to comment on that because it varies from product to product, obviously ACAM2000 product was a special case, if you like, was a very large volume in a short space of time, so that has different margin opportunities than a typical product that you'd be putting through each year on an annualized basis. So it's a difficult 1 to answer to be honest. And then again you with different products, some of the products are like-for-like, some of them aren't. Some of them are single dose vials some of them are 100 dose vials for example in the case of ACAM2000. So the kind of variability but clearly, the objective is that we – that the economics of this work for us as well as the logistics and the practicality of controlling our own product.

Steve McGarry - *Goldman Sachs - Analyst*

Okay, let me try it a different way. If you won the MVA contract and have the MVA contract and you're delivering it over say '05 to '07 time horizon. If you were doing all your filling and finishing what kind of margin enhancement do you reckon that would add, say if you didn't --

Gordon Cameron - *Acambis Plc - CEO*

You need to be clear here Steve, that Baxter is the fill and finish or the manufacturer fill and finisher for MVA. What this does, I think, is offer an alternative or a back up as part of our partnership proposal, so if you look at it 1 way you could -- do you think that we could -- that the partnership now has 2 fill and finish capabilities which is slightly different to what some of our competitors have.

Steve McGarry - *Goldman Sachs - Analyst*

Okay that's great. Thanks a lot.

Operator

The next question comes from the line of [indiscernible]. Please go ahead.

Unidentified participant

Good morning. 2 questions. Firstly on the JE vaccine. [indiscernible] are they expected to file BLA next year. 2 questions I'm not sure you'll like the first 1, but do you think that's do able? And what's your target filing date for JE vaccine?

Gordon Cameron - *Acambis Plc - CEO*

I don't want to comment specifically on [indiscernible] said, I think the filing of the BLA is a [function] of a whole host of things you could including clinical trials we well as getting manufacturing sorted etc., so I don't want to comment on the time lines that they've put out. I think from our perspective we've got a large Phase III trial to do, which we're intending to start in the second half of this year, which will be likely last through to the end of next year. So are we going to file a BLA in 2006? I think that's probably -- if it's going to be 2006 it'll be right at the end, probably more likely earlier 2007. I think we're just being realistic.

Unidentified participant

Just in the clinical program. Do you have to do 2 Phase III trials or just 1 giant Phase III?

Gordon Cameron - *Acambis Plc - CEO*

It's a safety and immunogenicity study, so it has a different objective and often the number of subjects for safety is higher than the number of subjects for immunogenicity. And also there the variability and we are planning to do a multi center sites and in multi geographical locations. And as I say some of those sites will be focused on safety and some of them will have an X component to them as well.

Unidentified participant

So there will be 2 separate trials or are we talking about 1 big trial with [indiscernible] with a [indiscernible] sub set of which there will be [indiscernible].

Gordon Cameron - *Acambis Plc - CEO*

The latter.

Unidentified participant

Just following up on the contracts in the U.S. Government. You've not really talked about [indiscernible] are you seeing [indiscernible] for MVA or [indiscernible] are they not doing anything, or what is the sense that you are going to [indiscernible] U.S. Government?

Gordon Cameron - *Acambis Plc - CEO*

We didn't make reference anything in the statement there hasn't been any significant contract wins in the period. Discussions are ongoing. Are people sitting on their hands waiting for MVA, I don't think so necessarily, to be honest. I think if people are looking to buy smallpox vaccines they're looking to buy ACAM2000 at this stage, so I think it's -- as I've said many times before, there's a whole variety of factors that going into the decision making process, and obviously the closer we get to licensor of the product, then I think the more likely it is to return some of these products -- to turn some of these discussions into firm orders.

Hence our reluctance earlier on in the year to try and be specific on the revenues other than just to state that we had a target at a similar level to what we achieved last year. And as David said we're not changing any specific guidance at this stage.

Unidentified participant

Thank you.

Operator

The next question comes from the line of Chris Redhead with Code Securities. Please go ahead.

Chris Redhead - *Code Securities - Analyst*

Hi guys. Just a quick question on the warm-base, most of my other questions have been answered. In term of the warm-base there was a article in the Boston Globe last week which was basically saying that U.S. Government's decision on whether the warm-base -- what level of warm-base they would give you, would obviously depend on what the level of other Government contracts were. They certainly weren't going to give you a guaranteed amount, they would top up, to give you a good manufacturing base based on what other demand was out there in the rest of the market. Do you want to comment on that?

Gordon Cameron - *Acambis Plc - CEO*

I think the only comment I would make is that that particular question has been asked about the Government offers as part of our discussions, and I think we've addressed the response that's given and the answer that both we and they were looking for.

Chris Redhead - *Code Securities - Analyst*

Okay.

Operator

The next question comes from the line of Robin Gilbert with Numis Securities. Please go ahead.

Robin Gilbert - *Numis - Analyst*

Good morning. Can you give us a little input on the production capacity you have for MVA in your team please?

Gordon Cameron - *Acambis Plc - CEO*

In a word "no". I think it's sensitive -- commercially sensitive, and I think at this stage it's probably not appropriate, but we will outline obviously all our capacity in our response to the RFP. And I think as we said many times, Baxter has today in place commercial scale manufacturing all MVA that meets the U.S. Government's requirements, even after the highest levels of change of procurement of vaccine so it's adequate to meet that need.

Robin Gilbert - *Numis - Analyst*

So is that an answer or not? I thought you said you wouldn't give an answer?

Gordon Cameron - *Acambis Plc - CEO*

That's as much as I'd have to say at this stage.

Robin Gilbert - *Numis - Analyst*

Right.

Operator

The next question comes from the line of [Sam Visarli] with Nomura. Please go ahead.

Sam Visarli - - *Analyst*

Good morning gentlemen. Firstly to congratulate you on how fantastically you've become at not really answering the questions, because I suspect the sensitivity of these things are quite important. But can I just ask, if you can answer, if you were to use the [indiscernible] that you've acquired, is it up to scratch in terms of already putting in as part of the proposal to the U.S. Government for an MVA contract for instance? And if it is, what would the chain then be, would it be manufacturing off-shore and bringing in and fill and finishing on-shore? Can you just comment on how that might end up looking?

Gordon Cameron - *Acambis Plc - CEO*

Are you talking about MVAs?

Sam Visarli - - *Analyst*

That's right. Only MVAs.

Gordon Cameron - *Acambis Plc - CEO*

I think again I just need to emphasize the point I made before. Baxter is designated manufacturer and seller and finisher of the MVA vaccine. They have capacity in place today with fill and finishing as well as obviously bulk production.

Sam Visarli - - *Analyst*

And is that all on-shore?

Gordon Cameron - *Acambis Plc - CEO*

That is in their facility in Europe.

Sam Visarli - - *Analyst*

Okay. If the U.S. were to say if it were giving to you a commercial advantage to have fill and finish done in the U.S. albeit a competitive sense, do you think that could make a difference?

Gordon Cameron - *Acambis Plc - CEO*

Well I think -- the way we presented it is the right way to present it, is that this could potentially be a back up or an alternative to include this part of the proposal, which I think from the U.S's standpoint a, it's on U.S. soil and b, it's an alternative filling site. So from a risk management perspective that's clearly -- that's attractive to the U.S. Government and therefore, as I said earlier on, the Partnership's hand is stronger than it was as of yesterday.

Sam Visarli - - *Analyst*

And if you go down that route, is the facility ready for use in that purpose, if that's what the U.S. Government asks for?

Gordon Cameron - *Acambis Plc - CEO*

I think the CapEx program that we've outlined, the clinical scale filling and manufacturing at the moment in the facility, and it would need upgrading over the course of the next several months to achieve that. And clearly we need to -- if and when we needed to do that for MVA, then we'd obviously discuss that with Baxter as well.

Sam Visarli - - *Analyst*

Fantastic. Thanks very much.

Gordon Cameron - *Acambis Plc - CEO*

Okay. Sam I'll just apologize for being somewhat --

Sam Visarli - - *Analyst*

No, I was just thinking how well you've let me off for doing it.

Gordon Cameron - *Acambis Plc - CEO*

I think you hit the nail on the head, there are some commercially sensitive discussions ongoing and prior to when we -- as and when we actually get some of these contracts awards, give the details at that point rather than speculate too much ahead of it.

Sam Visarli - - *Analyst*

I hope it was only a light hearted comment really.

Gordon Cameron - *Acambis Plc - CEO*

Thank you.

Sam Visarli - - *Analyst*

Okay.

Operator

There isn't a queue at this time. Would you like me to repeat the instructions, or would you like to go ahead and do your closing remarks now?

Gordon Cameron - *Acambis Plc - CEO*

If there are no further questions? Is that what you -- sorry I didn't quite hear.

Operator

Actually we have a question now from Robin Campbell with [Jefferies]. Please go ahead.

Robin Campbell - *Jefferies - Analyst*

Good morning gents. 2 questions if I may? Firstly on the MVA 2000. You've presented earlier end of April talking about the randomized several blind safety trials when 2 doses of the higher dose level. I wondered whether you could just share maybe the Sero conversion percent number after 1 dose? And also whether you intend having a 1 dose [indiscernible] as part of the Phase II trial you're intending to carry out in healthy adults? And secondly, I wondered if the revisions of the revised IND are in any way burdensome, and possibly could you lean towards a delay in the start of the West Nile trials?

Gordon Cameron - *Acambis Plc - CEO*

Let's start with the first 1. We haven't published data on the single dose, but I think it's fair to say that all the trials that we do in MVA from this trial and hereon, do [indiscernible] single versus [indiscernible] doses, obviously there's some data out there, as I recall for single dose vaccine. I think the belief is that it's likely to be a 2 dose vaccine for MVA and I suppose the data we have today in terms [indiscernible] of the next trials will attempt to obviously answer that question.

I think in terms of the West Nile, we've been through this process before in terms of making our own products and then putting our own [indiscernible] section in terms for an IND or for that matter for BLA, so we've made the J vaccine and ACAM2000 so we're used to putting in our own CMC section or amendments in the [indiscernible] and BLAs and so I don't anticipate that's likely to lead to any significant delay in the West Nile. That would be a [indiscernible] question?

Robin Campbell - *Jefferies - Analyst*

Yes it was. Thank you.

Operator

Now there are no questions at this time Sir.

Gordon Cameron - *Acambis Plc - CEO*

Okay. I think we've covered everything else today and as ever the Company's available to be contacted subsequently if need be. I thank you all for your time and for your questions and your interest in Acambis.

Operator

Ladies and gentlemen. This concludes your conference you may now disconnect. Good day.
